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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/480,850	06/07/95	PELLETT	P 1414.657

LEE, D EXAMINER

18N1/0430

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ART UNIT	PAPER NUMBER
1813	

DATE MAILED: 04/30/96

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/480,850	Applicant(s) Philip E. Pellett
	Examiner Danny Lee	Group Art Unit 1813

☒ Responsive to communication(s) filed on *This application has been examined* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *7 and 8* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *7 and 8* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The Art Unit location of your application in the Patent and Trademark Office has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1813.

The status of the related application(s) cited at the first page of the specification should be updated, if necessary, to ensure a properly completed file record.

The Examiner acknowledges Applicant's Preliminary Amendments, Paper Nos. 2 and 3, filed June 7, 1995. In view of Applicant's Preliminary amendments, the status of the claims is as follows: Claims 1-3,5,6 and 9-15 have been canceled; Claim 7-8 are currently pending before the Examiner.

The oath or declaration is defective. A new oath or declaration in compliance with 37 C.F.R. 1.67(a) identifying this application by its Serial Number and filing date is required. See M.P.E.P. 602.1 and 602.02. The oath or declaration is defective because: the copy of the oath is of such poor quality as to render the oath unreadable.

The following informality has been noted and requires correction in response to this Office Action. The attached form PTO 948 indicates that "Figures must Be Numbered Separately", i.e. "Figure 1A," "Figure 1B," etc. (see Item 7 and 37 CFR 1.84(i and j). While submission of formal drawings can be held in abeyance until such time as allowable subject matter is determined, Applicant is required to amend the Brief Description of the Drawings, if necessary, in response to this Office Action to properly reflect the required corrections of the Drawings.

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

The drawings are considered to be informal because they fail to comply with 37 CFR 1.84(a)(1) which requires black and white drawings using India ink or its equivalent.

Photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) or (b)(1) is granted permitting their use as formal drawings. In the event applicant wishes to use the drawings currently on file as formal drawings, a petition must be filed for acceptance of the photographs or color drawings as formal drawings. Any such petition must be accompanied by the appropriate fee as set forth in 37 CFR 1.17(h), three sets of drawings or photographs, as appropriate, and, if filed under the provisions of 37 CFR 1.84(a)(2), an amendment to the first

paragraph of the brief description of the drawings section of the specification which states:

> **"The file of this patent contains at least one drawing executed in color. Copies of this patent with color drawing(s) will be provided by the Patent and Trademark Office upon request and payment of the necessary fee."**

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 7-8 ~~is~~ are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11 of copending application Serial No. 08/475,064. Although the conflicting claims are not identical, they are not patentably distinct from each other because the generic composition of claim 11 in copending application, containing either recombinantly expressed gG-1 or gG-2 of HSV renders immediately obvious the species claims 7-8 of the instant application. It is noted that Applicant has filed both of the above referenced applications as divisional applications of parent application U.S.S.N. 07/691,728. However, review of the

parent application indicates that the claims of these two pending applications were not restricted in the parent application. It is further noted that in the parent application an original restriction requirement was made separating the subject matter of claims 7-8 from that of claim 11 (see 07/691,728, Paper No. 14, page 2). However, pursuant to applicant's arguments set forth in Paper No. 16, at page three, first full paragraph, the Examiner rejoined the subject matter of claims 7-8 and 11 (see Paper No. 17, page 2, first full paragraph). Therefore, the subject matter of claims 7-8 and 11 have not been restricted and are not protected from double patenting rejections under 35 U.S.C. § 121.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 7-8 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 7-8 are vague and indefinite in the recitation "substantially pure" since it is entirely unclear what level of purification would constitute a "substantially pure" sample. Applicant has defined "substantially pure" in the specification (see page 7, first full paragraph) but applicant's definition is equally vague and indefinite and fails to proscribe the metes and bounds of claims 7-8. Amendment of claims 7-8 to delete "substantially" would obviate this rejection. Claims 7-8 are further vague and indefinite in the recitation "HSV" since abbreviations should be avoided in the claims and it is unclear what HSV would correspond to. Amendment of claims 7-8 to recite "Herpes Simplex Virus" would obviate this rejection.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:

> **A person shall be entitled to a patent unless--**
>
> **(b) the invention was patented or described in a printed publication in this country or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> **A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**
>
> **Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.**

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 7-8 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over either of Lee et al. (Applicant's AA1) or Lee et al. (Applicant's AW). Applicant's claimed invention are directed to products of **recombinantly expressed** gG-1 or gG-2 antigens of HSV. Applicant's claims constitute Product-by-Process type claims. In a product-by-process claim, the process of producing the product is given no patentable weight. *In re Brown*, 173 USPQ 685, 688 (CCPA 1972). Lee et al. (AW) teaches a pure HSV gG-1 antigen immunoaffinity purified by mouse monoclonal H1379-2 antibodies(see page 112, second full paragraph). Further, Lee et al. (AA1) teaches a pure HSV gG-2 antigen immunoaffinity purified by mouse monoclonal H966 antibodies (see page 641,second column, last paragraph, page 642, first column, first full paragraph and page 643, first column, fourth full paragraph). Since the Patent Office does not have the facilities for examining and comparing applicants' composition with the compositions of the prior art references, the burden is upon applicants to show an unobvious distinction between the material, structural and functional characteristics of the claimed composition and the compositions of the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 1977).

Claims 7-8 are rejected under 35 U.S.C. § 103 as being unpatentable over Lee et al. (AA1) or Lee et al. (AW) in view of Luckow et al. (AO) or Matsuura et al. (AP). Lee et al. (AA1) and Lee et al. (AW) disclose purified gG-2 and gG-1 respectively as discussed above. Lee et al. (AA1) and Lee et al. (AW) do not disclose the production of gG-1 or gG-2 in a baculovirus expression system. Luckow et al. discloses the development of baculovirus expressions systems and the advantages of using such systems for "the very abundant expression of recombinant proteins, which are in many cases, antigenically, immunologically, and functionally similar to their authentic

counterparts" (see page 47, first column, first full paragraph). Luckow et al. also discloses many of the vectors suitable for baculovirus expression systems and the importance of particular leader sequences upstream from the polyhedrin gene ATG and their impact on protein production (see page 51, first column, last paragraph). Similarly, Matsuura et al. also discloses the uses and advantages of the baculovirus expression system and teaches "that the immediate 5' upstream sequences are important for high level expression" (see page 1234, Figure 1 and see page 1247, second full paragraph). Matsuura et al, also discloses vector pAcRP18 which has the "5' nontranslated leader sequence of the polyhedrin gene joined to the coding region of a foreign gene precisely at the translation initiation codon of the polyhedrin gen" of the claimed inventions. Neither Luckow et al. or Matsuura et al. teach the expression of gG-1 or gG-2 peptides in baculovirus expression systems. However, the level of ordinary skill in the genetic engineering art is exceptionally high and, absent convincing objective evidence to the contrary, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to express the gG-2 protein of Lee et al. (AA1) or the gG-1 protein of Lee et al. (AW) in the baculovirus expression system of Luckow et al. or Matsuura et al. for the expected benefit of obtaining high levels of expression of gG-1 and gG-2 proteins. One of ordinary skill in the art would have been motivated to express the proteins in a baculovirus system since Luckow et al. and Matsuura et al. disclose the numerous advantages of baculovirus expressions systems, the importance of retaining an intact 5' nontranslated leader sequence of the polyhedrin gene and one of ordinary skill would have had a reasonable expectation of success since Luckow et al. and Matsuura et al. both establish that the baculovirus system produces significant amounts of peptides and that such

peptides "are in many cases, antigenically, immunologically, and functionally similar to their authentic counterparts."

No claim is allowed.

Papers relating to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 located in Crystal Mall 1. The Fax number for Art Unit 1813 is (703) 305-7939. All Group 1800 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Danny Lee whose telephone number is (703) 305-7245. The Examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM, (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christine M. Nucker, can be reached at (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Danny Lee
Art Unit 1813

dl
April 23, 1996

ROBERT D. BUDENS
PRIMARY EXAMINER
GROUP 1800